DEC - 6 2004

K040865

C. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (in Accordance with SMDA of 1990)

AESCULAP STERILCONTAINER FOR STERRAD

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Matthew M. Hull, RAC
800-258-1946 x 5072 (phone)
610-791-6882 (fax)

TRADE NAME: Sterrad Compatible Aesculap Sterilcontainer

COMMON NAME: Sterilization Container Wrap

DEVICE CLASS: Class II

PRODUCT CODE: 80 FRG

CLASSIFICATION: 880.6850 – Wrap, Sterilization

REVIEW PANEL: General Hospital

INDICATIONS FOR USE

The Aesculap Sterilcontainer is a reusable sterilization container system intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container system is compatible for use with the Sterrad 100S.

DEVICE DESCRIPTION

The Sterrad Compatible Aesculap Sterilcontainer is designed as a container system that will allow for sterilization and storage of other medical devices. This container is designed to be compatible for use with the Sterrad sterilization processes (100S). The container is made from non-anodized Aluminum and utilizes a disposable (single use) polypropylene filter.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications 510(k)'s" for Sterrad Compatible Aesculap Sterilcontainer was completed. Sterilization testing results demonstrate the Aesculap Sterilcontainer for Sterrad is substantially equivalent to other Sterilization Containers currently on the market.

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Sterrad Compatible Aesculap Sterilcontainer is substantially equivalent to our currently marketed Sterilcontainers. Additionally we feel it is substantially equivalent to the sterilization containers marketed by Allegiance Healthcare (Genesis) and Case Medical (SteriTite).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 2004

Mr. Matthew M. Hull
Regulatory Affairs Manager
Aesculap, Incorporated
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K040865
Trade/Device Name: Aesculap Sterrad 100S Compatible Sterilcontainer
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: November 11, 2004
Received: November 12, 2004

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

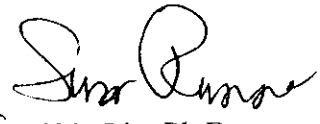
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE STATEMENT

510(k) Number: K040865/S2

Device Name: Aesculap Sterrad Compatible Sterilcontainer

Indication for Use:

The Aesculap Sterilcontainer is a reusable sterilization container system intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container system is compatible for use with the Sterrad 100S.

SterilContainer Sterrad 100S Compatible Containers		
Description	**Size (L"xW"xH")**	**Item #**
Full Size Perforated Bottom	23 x 11 x 4	JM440
Full Size Perforated Bottom	23 x 11 x 5 1/3	JM441
Full Size Perforated Bottom	23 x 11 x 6	JM442
Full Size Perforated Bottom	23 x 11 x 8	JM444
¾ Size Perforated Bottom	18 ¼ x 11 x 4	JM740
¾ Size Perforated Bottom	18 ¼ x 11 x 5 1/3	JM741
¾ Size Perforated Bottom	18 ¼ x 11 x 6	JM742
½ Size Perforated Bottom	11 ¼ x 11 x 4	JM340
½ Size Perforated Bottom	11 ¼ x 11 x 5 1/3	JM341
½ Size Perforated Bottom	11 ¼ x 11 x 6	JM342
½ Size Perforated Bottom	11 ¼ x 11 x 8	JM344
¼ Size Perforated Bottom with Lid	12 x 7 x 2 ½	JM094
¼ Size Perforated Bottom with Lid	12 x 7 x 5	JM096
Full Size Lid		JM489
¾ Size Lid		JM789
½ Size Lid		JM389
¼ Size Lid		See JM094 & JM096

Prescription Use _____ or Over-the-Counter Use X

(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Janette M. Cham acting Chief INC BR 12-03-04

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040865